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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/392,842 09/09/99 SAWAN

S SUR-008

021323 HM12/0410  
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EXAMINER

SHARAREH, S

ART UNIT

PAPER NUMBER

1619

DATE MAILED:

04/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/392,842

Applicant(s)

SAWAN ET AL.

Examiner

Shahnam Sharareh

Art Unit

1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- 1) ☒ Responsive to communication(s) filed on 1/22/2001.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-88 is/are pending in the application.
- 4a) Of the above claim(s) 1-57, 72-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 58-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-57 and 72-88 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6
- 17) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other:

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### **DETAILED ACTION**

Applicant's provisional election with traverse of Group II, and the bigunide polymer specie of poly(hexamethylenebiguanide), and the water-insoluble organic compound specie methylene-bis-N,N-diglycidylaniline, in Paper No. 8 is acknowledged. Claims 58-70 reads on the elected species and the elected invention. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Restriction requirement as set forth in Paper No. 7 is thus proper and is made Final.

Accordingly, Claims 1-57, 72-88 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. This application contains claims 1-57, 72-88 drawn to an invention nonelected without traverse in Paper No. 8 (it is noted that applicant elected with traverse but did not actually make a traversal). A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Priority***

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 58-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 58 recites the limitation of "the duration of efficacy of a dermal antiseptic formulation". It is not clear which duration of efficacy of which dermal formulation is applicant claiming as an invention. The limitation appears to lack antecedent basis. The metes and bounds of the instant recitation is vague.

Claim 58 recites the limitation "the formulation" in line 5 of the claim. There is insufficient antecedent basis for this limitation in the claim. It is not clear to which formulation is Applicant referring

Claim 58 recites the limitation "thereby enhancing the antimicrobial efficacy of the antiseptic formulation by imparting residual antimicrobial activity". The claim appears incomplete.

First it is not clear to which enhancing activity is applicant referring? Is the activity of the polycationic antimicrobial material, the dermal antiseptic or the resultant mixture? Second, what is a "residual antimicrobial activity" and how is it imparted. The metes and bounds are not clear. Third, the claim appears to lack essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: administering, enhancing antimicrobial efficacy, forming a barrier and imparting residual antimicrobial activity. Finally, the recitation of "capable of forming"

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does not render any barrier being formed. Examiner suggest substitution with a more descriptive phrase such as "being a".

Claim 61 is vague. It is not clear which to which polycationic material is the metal bound. It appears that the polycationic material comprise a biguainde polymer and a metal wherein the metal is bound to the biguainide polymer. Clarification is requested.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 58-71 are rejected under 35 U.S.C. 102(a) as being anticipated by Sawan et al WO-98/18330 ('330).

The instant claims are directed to methods duration of efficacy of a dermal antiseptic formulation comprising mixing a polycationic antimicrobial material and a dermal antiseptic formulation, forming an antiseptic barrier around the surface of the dermal antiseptic formulation, enhancing the antimicrobial activity of the dermal antiseptic formulation, wherein the polycationic antimicrobial material comprising a

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biguanide polymer such as poly(hexamethylenebiguanide) (PHMB), a water-insoluble organic compound specie methylene-bis-N,N-diglycidylaniline (MBDGA), and an antimicrobial metal such as silver.

'330 patent discloses methods of preparing a solution of PHMB polymers crosslinked by MBDGA, coating an article with the solution, and then immersing the coated article in a silver iodide/potassium iodide alcohol solution (pages 24-26, and example 17). '330 disclose that the coated article have higher antimicrobial activity after being coated, thus their antimicrobial activity is enhanced (example 4-6, claims 1-37). Accordingly, '330 meets the limitations of the instant claims.

Claims 58-61 rejected under 35 U.S.C. 102(b) as being anticipated by Brown US Patent 4,643,181.

The policy of the US PTO is to give pending claims their broadest reasonable interpretation. The instant open-ended claims comprise and do not exclude any components essential to the operability of the cited prior art patents. Applicant is suggested to draw a clear mark of demarcation between the cited prior art and the claimed invention. Brown discloses antimicrobial coating compositions comprising an antimicrobially effective amount of polycationic polymer such as PHMB. Brown disclose adjusting the biocidal activity of a hydrophobic acrylate-type adhesive and enhancing its activity against *S. aureus* (col 7 lines 25-55, claims 1-7). Accordingly, Brown meets the limitations of the instant claims

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Claims 58-71 rejected under 35 U.S.C. 102(b) as being anticipated by Sawan et al WO 95/17152 ('152).

'152 discloses antimicrobial coating compositions comprising PHMA-MBDGA-silver coating mixtures, and methods of using them to enhance antimicrobial activity of various articles or topical compositions such as eyecare products (35-39, page 40, paragraph b-d, pages 46-49. Claims 1, 18-20, 29-53). '152 patent meets the limitations of the instant claims.

Claims 58-71 are rejected under 35 U.S.C. 102(e) as being anticipated by Sawan et al US Patent 5,817,325.

Sawan et al disclose methods of enhancing devices and formulations comprising a PHMB-MBDGA-silver coating on a device or a dermal composition, (col 15-17). Thus, Sawan et al meet the limitations of the instant claims.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 58-71 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-38 of U.S. Patent No. US 6,180,584, claims 1-6 US Patent 6,030,632, claims 1-9, US Patent 5,869,072, claims 1-9, US Patent 5,817,325. Although the conflicting claims are not identical, they are not patentably distinct from each other because each of the cited patents are directed to compositions comprising a biguanide material, a metal material such as silver compounds and a cross linker, and/or methods of using such compositions to improve the antimicrobial activity of an article or a secondary formulation.

For example claims of the patent 6,018,584 are directed methods of improving an antimicrobial layer on a substrate by applying the invented disinfectant composition on the substrate (claims 1, 27-33). Accordingly, the instant claims are obvious modification of the already patented claims.

### **Conclusion**

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.




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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss  
april 4, 2001



DANA DUDASH  
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